



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 17 1999

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Mr. Robert B. Clark
Director/Team Leader
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Re: Docket Nos. 99P-1172/CP1 and 98N-0056

Dear Mr. Clark:

This letter responds to your citizen petition submitted on April 23, 1999, requesting that the Food and Drug Administration (FDA) add alatrofloxacin mesylate to the priority section of the List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population (Docket No. 98N-0056). The Agency has evaluated your petition and concluded that alatrofloxacin mesylate meets the criteria for inclusion on the priority section of the list. Accordingly, your petition is granted.

FDA has added alatrofloxacin mesylate to the priority section of the list for the treatment of the following conditions: Nosocomial pneumonia; community acquired pneumonia; complicated intra-abdominal infections, including post-surgical infections; gynecologic and pelvic infections; prophylaxis of infection associated with elective colorectal surgery; and complicated skin and skin structure infections, including diabetic foot infections.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

98N-0056

LET6

CROSS FILE SHEET

File Number: 99P-1172/PAV1

See File Number: 98N-0056/LET6